

C.F.R. §1.17(c) for a three-month extension of time (or for any necessary fees related to their response)



Amendments

In The Claims

In response to the Office Action dated August 29, 2001, we request entry of the amendments to the claim 44 as submitted herewith. Applicants provide as an attachment a "clean" (unmarked-up) version of the claims and a "marked-up" version of the claims showing the amendments made.

The submitted marked-up version of the claims and paragraphs of the specification follow standard amendment rules, wherein added text has been underlined and deleted text has been bracketed.

Explanation of the Amendments

Claim 44 was amended to correct a typographical error. Claim 44 initially started as "he method . . ." which should be "The method . . ." No support is needed to make correction of a misspelling.

Remarks To The Detailed Action

Claim Objections

(1) Claim 44 was objected to because of the following informalities.

Claim 44 begins with the phrase "he method II which should be "The method...". Appropriate correction is required.

Applicants have amended claim 44 to make the typographical correction as required, and respectfully request the present rejection be removed.

AMENDED CLAIMS

13. An indwelling catheter comprising:
an elongate body having a proximal end, a distal end, a tissue-contacting surface, and at least one interior lumen therethrough; and
an external fitting coupled to the proximal end;
wherein the tissue-contacting surface of the elongate body comprises a polymer in which a steroidal anti-inflammatory agent is intimately mixed, the steroidal anti-inflammatory agent being present in a concentration of between .1% and 5% of the steroidal agent in the polymer (w/w).

14. The indwelling catheter of claim 13 further comprising one or more helical coils formed in the elongate body between the proximal and distal ends.

15. The indwelling catheter of claim 13 wherein the polymer is selected from the group of polyurethanes, silicones, polyamides, polyimides, polycarbonates, polyethers, polyesters, polyvinyl aromatics, polytetrafluoroethylenes, polyolefins, acrylic polymers or copolymers, vinyl halide polymers or copolymers, polyvinyl ethers, polyvinyl esters, polyvinyl ketones, polyvinylidene halides, polyacrylonitriles, copolymers of vinyl monomers with each other and olefins, and combinations thereof.

16. The indwelling catheter of claim 15 wherein the polymer is selected from the group of polyurethanes, silicones, or combinations thereof.

17. The indwelling catheter of claim 13 wherein the anti-inflammatory agent is a glucocorticosteroid.

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18. The indwelling catheter of claim 17 wherein the glucocorticosteroid is selected from the group of cortisol, cortisone, fludrocortisone, Prednisone, Prednisolone, 6 α -methylprednisolone, triamcinolone, betamethasone, dexamethasone, beclomethasone, aclomethasone, amcinonide, clebethasol, clocortolone, derivatives thereof, and salts thereof.

19. The indwelling catheter of claim 18 wherein the glucocorticosteroid is dexamethasone, a derivative thereof, or a salt thereof.

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24. The indwelling catheter of claim 13 wherein the tissue-contacting surface further includes heparin.

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27. A method of modulating tissue encapsulation of an indwelling catheter comprising implanting the indwelling catheter into a patient, wherein the indwelling catheter comprises:

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- an elongate body having a proximal end, a distal end, a tissue-contacting surface, and at least one interior lumen therethrough; and
- an external fitting coupled to the proximal end;

wherein the tissue-contacting surface of the elongate body comprises an overcoating of a polymer in which a steroidal anti-inflammatory agent is intimately mixed at a concentration of between .1% and 5% of the steroidal anti-inflammatory agent in the polymer (w/w).

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29. A method of modulating degradation of an indwelling catheter comprising implanting the indwelling catheter into a patient, wherein the indwelling catheter comprises:

- an elongate body having a proximal end, a distal end, a tissue-contacting surface, and at least one interior lumen therethrough; and
- an external fitting coupled to the proximal end;

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wherein the tissue-contacting surface of the elongate body comprises a polymer intimately mixed with a steroidal anti-inflammatory agent and wherein the solid weight of the steroidal anti-inflammatory agent is between .1% and 5% of the total solid combined weight of the polymer and the steroidal anti-inflammatory agent.

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33. A method of making an indwelling catheter comprising:
providing an elongate body having a proximal end, a distal end, a tissue-contacting surface, and at least one interior lumen therethrough;
wherein the tissue-contacting surface comprises an overcoat of a polymer intimately mixed with a steroidal anti-inflammatory agent [is incorporated] at a concentration of between .1% and 5% of the steroidal anti-inflammatory agent in the polymer (w/w); and
coupling an external fitting to the proximal end of the elongate body.

34. The method of claim 33 wherein the step of providing an elongate body comprises intimately mixing the steroidal anti-inflammatory agent with the polymer in a solvent and applying the mixture to the elongate body to form a tissue-contacting surface.

36. The catheter of Claim 13, wherein the polymer is a non-porous polymer.

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37. The catheter of Claim 13, wherein the steroidal anti-inflammatory agent is between .1% and 1% of the total solid combined weight of the polymer and the steroidal anti-inflammatory agent.

38. The catheter of Claim 37, wherein the steroidal anti-inflammatory agent is selected from the group consisting of dexamethasone and beclomethasone.

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39. The catheter of Claim 13, wherein the steroidal anti-inflammatory agent is impregnated into the polymer of the tissue-contacting surface.

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41. The method of Claim 29, wherein the steroidal anti-inflammatory agent is impregnated into the polymer of the tissue-contacting surface.

43. The method of Claim 29, wherein the steroidal anti-inflammatory agent is between .1% and 1% of the total solid combined weight of the polymer and the steroidal anti-inflammatory agent.

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44. The method of Claim 43, wherein the steroidal anti-inflammatory agent is selected from the group consisting of dexamethasone and beclomethasone.
